



Bisphenol A – Based Materials are Safe for Use

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PlasticsEurope
Association of Plastics Manufacturers
Polycarbonate / Bisphenol A group

- **Global PC/BPA Group**
- **Bisphenol A – Why is there a debate?**
- **Bisphenol A – Myths and facts**
- **Food safety and consumer exposure**
- **Summary authorities opinions**

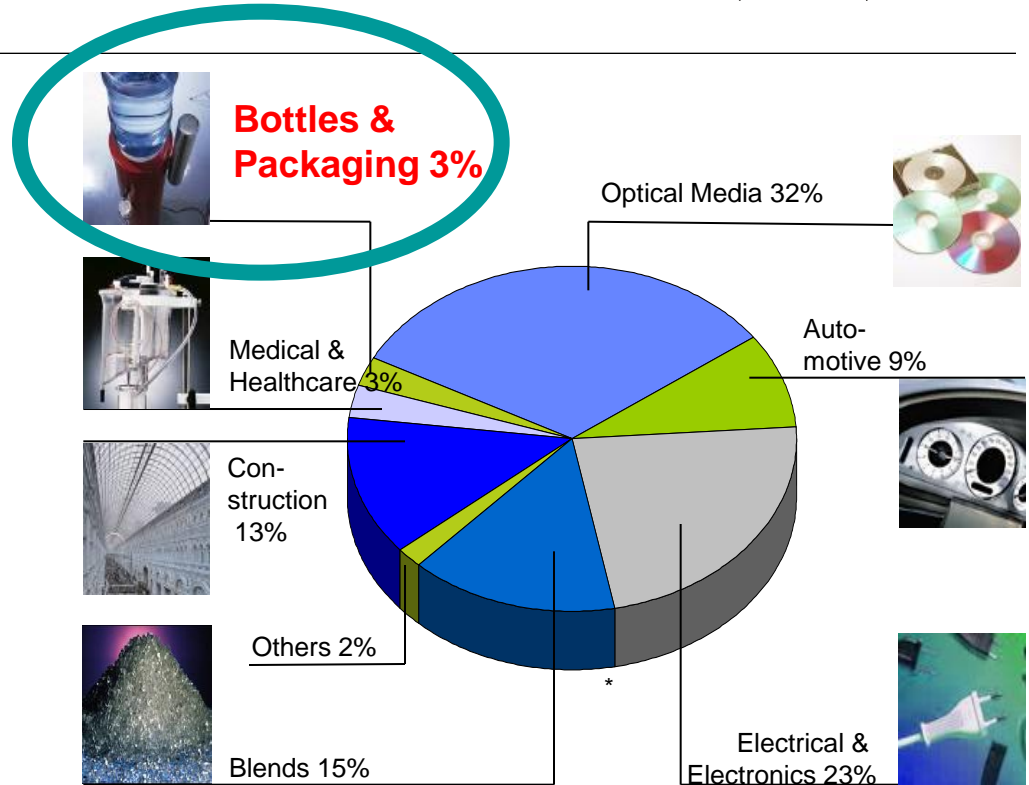
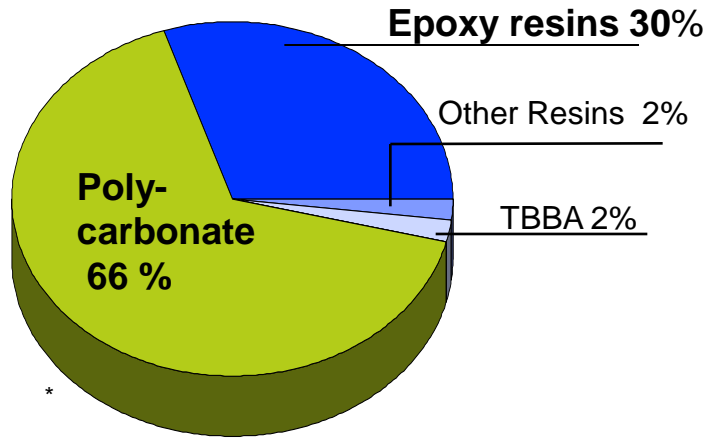


- **Global coalition of bisphenol A and polycarbonate resin manufacturers**
 - Key focus on health and environmental aspects of bisphenol A and polycarbonate
 - Integrated global structure with regionally tailored activities in US (ACC), Europe (PlasticsEurope), Japan, Korea. Support to and cooperation with local association teams for country-specific topics, e.g. DK: Plastindustrien.

Strategic Goals

- **Resolve scientific uncertainty**
 - Objective: sponsor high-impact research as basis for sound science assessments and analyse published science for validity and relevance
- **Prevent unjustified regulation**
 - Objective: ensure decisions are based on sound science
- **Prevent unjustified product de-selection**
 - Objective: maintain customer/consumer confidence in safety and quality of products

How are BPA and PC Used?



Global Bisphenol A production volume 2008:
app. 4.9 million tonnes*

Global polycarbonate production volume 2006:
approx. 2.9 million tons*

BPA is an **intermediate** used mainly in the production of polymers such as polycarbonate and epoxy resins.** Products contain only **trace levels** of BPA.

Hidden danger in baby bottles?



Danmark forbyder hormon-stof i sutteflasker

Des sénateurs proposent l'interdiction du bisphénol A

A Paris des biberons sans BPA

Investigation: Scandal of danger chemical in baby bottles

Water coolers banned

**Plastik kan give
hjerte-kar-
sygdomme**

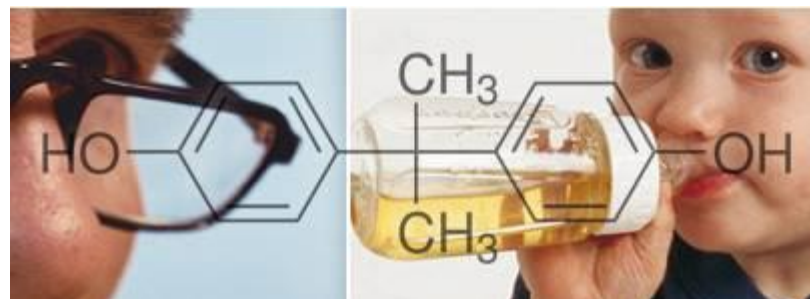
**Scientists
declare war
over BPA**



Politisk glæde over sutteflaskeforbud

Denmark bans BPA in packaging for children

- Weak estrogen-like potential
- BPA in focus of explorative research: e.g. suspected effects at ultra trace levels, „Low-Dose“
- Findings in cell cultures and in animal studies are presented to the media as evidence of an effect in humans before any discussion in the scientific community
- Consumer use via food contact materials; biomonitoring data provide proof of exposure
- Continued (policy-driven) regulatory activities regarding BPA
- NGOs use BPA in the political debate
- Media uses BPA to gain attention



Fact is...

- BPA has a rich and robust database on (eco)toxicity, metabolism, pharmacokinetics, human exposure
- More than 1000 toxicological studies on BPA have been evaluated by regulatory bodies around the world:
 - High quality, statistical robust guideline studies done under GLP which focus on the relevant route of exposure like food uptake
 - Non-guideline, explorative studies
- Exploratory studies for instance
 - Observed effects which are not reproducible under accepted scientific conditions
 - Have no or insufficient quality control (no GLP or not according to GLP)
 - Use cell cultures
 - Use irrelevant routes of exposure (e.g. implanted infusion pump)
 - Use limited number of doses or test animals (insufficient statistical power)

- BPA has low acute toxicity
- BPA is not carcinogenic or mutagenic
- BPA does not adversely effect reproduction or development at any realistic dose
- BPA shows weak estrogenic effects only at extreme high dose levels which will never be reached in daily life (comparable situation to natural phyto-estrogens in soybeans, carrots, tofu etc.)
- BPA is efficiently “metabolised” and rapidly excreted after oral exposure. (e.g. for adults: half-life ~ 4hrs based on human data)
- The “metabolites” have been shown to be non-estrogenic
- BPA does not cause “low-dose” endocrine related reproductive or developmental effects in large scale robust guideline studies. Reported “low-dose” effects have not been replicated and confirmed.

Myth:

Claims link BPA exposure to:

- Cancer
- Early puberty
- Birth defects, miscarriage
- Diabetes, obesity, heart disease
- Hyperactivity, neural-behaviors

Reality

Claimed effects are not supported by weight of scientific evidence

Other claims:

- ~~Low exposure linked to effects~~
- ~~BPA is a plasticizer~~
- ~~Microwaving ↑↑ migration~~

Reality:

- ✓ „Low dose” effects not replicated
- ✓ BPA is chemical building block
- ✓ Not linked to increased migration

Food Safety and Consumer Exposure

- BPA (PC) is **authorized for food contact** applications by regulatory bodies worldwide
- In Europe, BPA complies with the requirements of directive 2002/72/EC and is listed under Annex II
- The current safe level the Tolerable Daily Intake (TDI) in EU is 0.05 mg/kg body weight/day (EFSA 2007). The same value is used as US Reference Dose
- The European Specific Migration Limit (SML) is still set at 0.6 mg/kg food based on EFSA 2002



BPA presents little or no risk to human health:

- Demonstrated by **comprehensive risk assessments on BPA**
- Supported by government bodies worldwide



EU Risk Assessment: Articles Based on BPA can Safely be Used



Most stringent EU risk assessment concluded that there is no concern regarding consumer use of BPA-based articles e.g. made from PC (June 2008); Exposure of small children was specifically addressed

Link:

http://ecb.jrc.it/documents/Existing-Chemicals/RISK_ASSESSMENT/ADDENDUM/bisphenola_add_325.pdf

European Chemicals Bureau (K. Aschberger) 2008:

„ We found that the *margin of safety is high enough* in relation to consumer exposure of BPA in plastic packaging and, as a result, there is *no need for further information, testing or risk reduction measures* beyond those which are being applied already“

EFSA is constantly reviewing newly published science on BPA

- **2007, EFSA, based on the now available sound scientific data, increased the Tolerable Daily Intake by factor of 5 to 50 µg/kg b.w.**

„...low-dose effects of BPA in rodents have not been demonstrated in a robust and reproducible way“ Link: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620835386.htm

- **2008, EFSA reaffirmed its conclusion that BPA is safe in food containers, baby bottles and water bottles**

“provides a sufficient margin of safety for the protection of the consumer, including foetuses and newborns.” Link: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902017373.htm

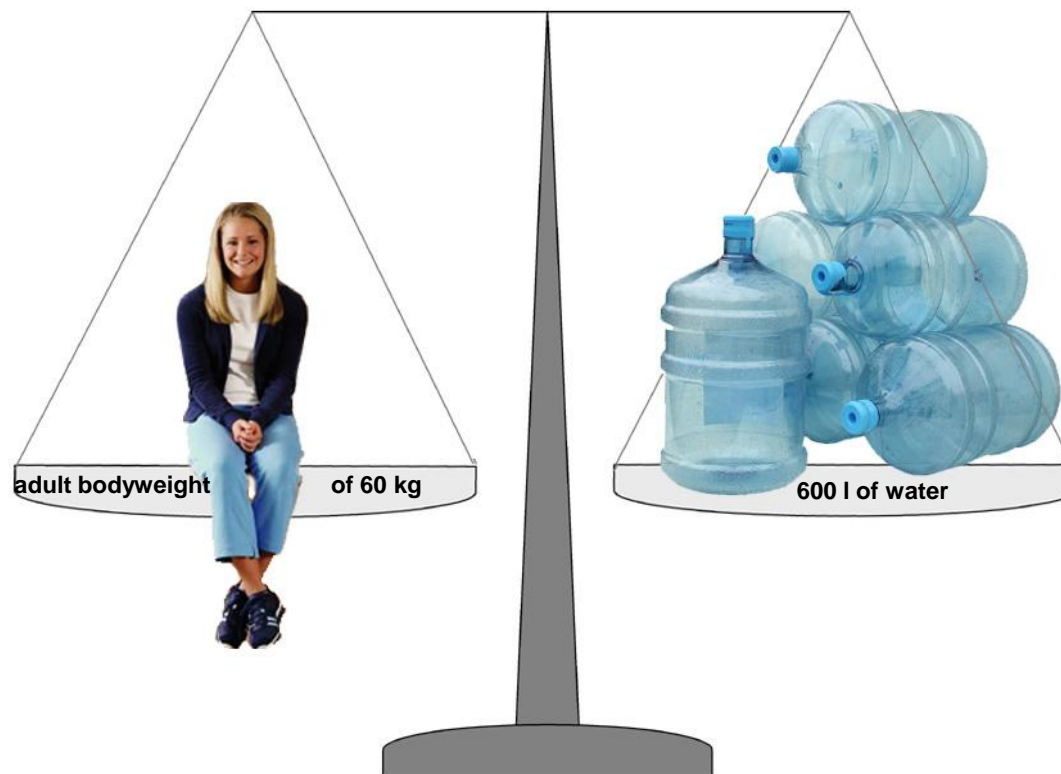
- **2009, EFSA re- confirmed their position on BPA in “Food Production Daily”**
“None of the studies which have so far been published have brought into question EFSA’s previous findings on BPA. EFSA is aware of the study recently published by the Harvard School of Public Health...”

- Link: <http://www.foodproductiondaily.com/Quality-Safety/European-safety-watchdogs-reaffirm-belief-in-safety-of-BPA>

- **Currently, EFSA’s evaluation of new scientific studies including the industry sponsored DNT study ongoing; updated opinion expected for May 2010**

EU Authorities Safety Limits vs. Typical Migration Value of BPA

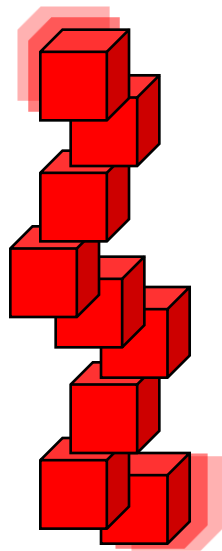
Reaching the TDI is clearly impossible!!



A person weighing 60 kg would have to eat the equivalent of his/her own body weight of canned food per day, or drink 600 liters of water from PC bottles, to reach the safety limit TDI !

To reach the safe TDI of $50 \mu\text{g}/\text{kg bw}/\text{d}$ a child would have to suck for 4 hours $200,000^*$ PC block-shaped toys, which is equivalent to

a PC cuboid toy snake of



3340 meter

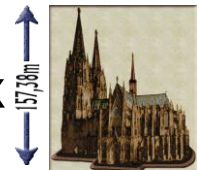


Clearly impossible!!

a PC cuboid toy tower of



13 x



2000 meter: 13 x taller
than Cologne Cathedral

*** Assumptions:**

PC cuboid toy: $1.67 \text{ cm} \times 1 \text{ cm}$, with 6 calculated areas $\rightarrow 10 \text{ cm}^2$ surface;

BPA migration into artificial saliva after 4 hrs – industry internal data: $0.025 \mu\text{g}/\text{dm}^2 \rightarrow 0.00025 \mu\text{g}/\text{kg bw}/\text{d}$ (Intake of a 10 kg child sucking a PC surface of 10 cm^2 over 4h)

The Denmark Case...

Comprehensive peer-reviewed study “*Developmental Neurotoxicity Study of Dietary Bisphenol A in Sprague-Dawley Rats*” (Toxicol. Sci. Stump et al. 115 (1), 167-182)

- Danish National Food Institute (NFI):
 - Regards study to not fully close knowledge gaps raised by some “low dose” studies
 - Addresses uncertainties in regard to minor findings in learning capacity;
 - However, evaluation is failing to give scientific reasoning and does not give evidence of adverse effects
- In contrast, The U.S. Food and Drug Administration (FDA) publicly confirmed the authors’ conclusion: BPA is not a developmental neurotoxicant
 - FDA found no evidence of effects
 - Because of a lack of consistency and dose-dependence for the endpoint of learning capacity FDA did not support the view of Ulla Hass and the Danish NFI

<http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2010-N-0100> (under supporting & related material)

U.S. FDA concluded: No evidence that BPA is a developmental neurotoxicant in rats at any dose tested



- In February 2010 the Danish Parliament voted to request the Minister for Food, Agriculture and Fisheries to work towards a ban of BPA use in food contact materials for children under 3 (toys exempted).
- On March 26 the Danish Government announced to establish a temporary national ban on bisphenol-A based food contact materials in products aimed for children aged 0-3 as a precautionary measure
 - Evaluation of DNT study by Danish National Food Institute expert used as reasoning
 - Restriction applies e.g. to baby feeding bottles, feeding cups and canned infant formula
- The decision was implemented in Danish Law*. It will come into force in Denmark as of July 1, 2010, following a 3 months transition period during which existing stocks must be sold out.

The Danish proposal is in contrast to the currently enforced “European Directive on Plastics in Contact with Food”

Danish announcement done under the safeguard clause of EU rules on food contact materials

- Denmark has to notify the revised Danish Orders regarding BPA to the EU Commission and EU Member States, however notification still not on the EU Commission's website
- EU Commission has to react to the notification: the Danish restriction towards BPA on the agenda of EU Commissions' Member State meeting (DG SANCO standing committee), May 19, 2010
- Next steps of the EU Commission regarding enforcement of Danish ban are depending on new EFSA opinion and EU Member States decision

The Danish decision

- **Is not based on sound science and evidence of adverse effects and by that sets a negative precedent for any future assessment of chemicals**
- **Does not show any specific implications for the Danish population**
- **Creates an unnecessary barrier to trade in the EU and globally, creating consumer, business and investment uncertainty**
- **Ignores the question about the safety of available substitutes**

Other Authority opinions...



United Kingdom

Andrew Wadge,
Chief Scientist FSA,
(April 2010)

"We will always base our advice to consumers on the best available scientific evidence. Independent scientific experts advise that current levels of exposure to BPA are not harmful. The European Food Safety Authority review concluded that low-dose effects of BPA in rodents have not been demonstrated in a robust and reproducible way, and so cannot be used as pivotal studies for risk assessment."



Germany

BfR (April 2010)
German government
(June 2009)

"After careful scientific assessment of all available studies, in particular studies in the low dose range of bisphenol A, EFSA and BfR come to the conclusion that there is no health risk from BPA for infants and small children when the polycarbonate bottles are used in the normal way."

"For hardly any other chemical the toxicological and exposure data are in such a manner extensive and suitable to execute a valid risk assessment and derive a safe TDI on them as for BPA. [...]"



France

AFSSA, March 2010

"AFSSA reiterates that the toxicity studies in which BPA was administered ... and which were conducted according to international standards, have not so far characterized health risks at current human levels of exposure." However, in a stakeholder approach, France voiced some uncertainties related to children, gave advise how to minimize exposure



Spain

AESAN, April 2010

Richter, PC/BPA Group, 2010-05-06

"Under these circumstances, and taking into account the scientific data and the EFSA recommendation, the Spanish safety authority, like the large majority of the other national safety authorities in Europe, does not think that there is a reason to take any measures with regard to the substance at the moment."



Switzerland



BAG, February 2009

“The SFOFH [...] is of the opinion that the ingestion of Bisphenol A through foodstuff does not pose a risk to the buying public. This is also applies for newborns and infants.”

“A ban on BPA would inevitably cause manufactures of packaging and consumer products (food contact materials) to have to switch to other substances, the toxicity of which is less well known. This would mean a well characterized risk would be replaced with a conspicuously unpredictable risk.”



Belgium



June 2009

Health Minister Ms
Laurette Onkelinx

“[...] The results of the analyses of AFSCA (Belgian Food Safety Agency) [...] show that all values measured were far inferior to the migration limits. [...] Based on these conclusions and data, no complementary measure is envisaged, either at EU or Member State level [...].”



The Netherlands



voedsel en waren autoriteit

November 2008

“The researched polycarbonate baby bottles have no demonstrable migration of BPA into the simulants for fruit juice and milk. This means that the bottles are safe for use for babies and toddlers with respect to BPA. “



Ireland



June 2009

“The advice is that there's no need to avoid BPA. [...]” Rhodri Evans, chief toxicologist



January 2010

“FSANZ has assessed the risk to infants from exposure to BPA and concurred with the conclusions reached by the US FDA and the EFSA that the levels of exposure are very low and do not pose a significant health risk. The move by overseas manufacturers to stop using BPA in baby bottles is a voluntary action and not the result of a specific action by regulators.”

The screenshot shows the website www.bisphenol-a-europe.org. The main banner features a large image of a circular skylight with workers on it, and a blue text box that reads: "Food contact materials based on BPA are safe" attributed to Japanese Ministries MHLW, METI. Below the banner is a green navigation bar with links: Home, What is Bisphenol A?, Benefits, Safety, Myths, Science, News, Legislation, e-Library, and FAQs. The page also includes a search bar, RSS feed, and print options. A section titled "About Bisphenol A" provides a brief overview of the chemical compound and its applications. There are also sections for "Bisphenol A Facts" and "Bisphenol A News".

* Website available in English, German, French and Spanish language

www.bisphenol-a-europe.org

BPA value chain is committed to the safety of their products

- BPA is an intermediate used mainly in the production of polymers such as polycarbonate and epoxy resins

Regulatory bodies around the world have approved BPA for food contact

- BPA has a rich and robust database on (eco)toxicity, metabolism, pharmacokinetics, human exposure
- BPA does not cause “low-dose” endocrine related reproductive or developmental effects in large scale robust guideline studies. Reported “low-dose” effects have never been replicated and confirmed.

Proposed restrictions on use of BPA in Denmark

- Are not based on sound science and evidence of adverse effects
- Create an unnecessary barrier to trade in the EU and globally, creating consumer, business and investment uncertainty
- Ignores the question about the safety of available substitutes



Based on the weight of the scientific evidence it has been demonstrated that when used as intended BPA-based food contact materials are safe.



Thank You for Your Attention